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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/692,785	10/27/2003	Egisto Boschetti	9676-314-999	1038
20582	7590	11/16/2005	EXAMINER	
JONES DAY 51 Louisiana Aveue, N.W WASHINGTON, DC 20001-2113			JONES, DAMERON LEVEST	
			ART UNIT	PAPER NUMBER
			1618	

DATE MAILED: 11/16/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/692,785

Applicant(s)

BOSCHETTI, EGISTO

Examiner

D. L. Jones

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 9/15/05; 8/29/05; & 10/27/03.
2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1,4-11,15-30 and 56 is/are pending in the application.
4a) Of the above claim(s) 22-30 is/are withdrawn from consideration.
5) ☐ Claim(s) _____ is/are allowed.
6) ☒ Claim(s) 1,4-6,8,9,11,15-20 and 56 is/are rejected.
7) ☒ Claim(s) 7,10 and 21 is/are objected to.
8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☒ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☒ Certified copies of the priority documents have been received in Application No. 09/419,114.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date 9/15/05; 8/29/05.
4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____

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ACKNOWLEDGMENTS

1. The Examiner acknowledges receipt of the amendment filed 8/29/05 wherein claims 1 and 11 are amended; claims 2, 3, 12-14, and 31-55 are canceled; and claim 56 is added.

Note: Claims 1, 4-11, 15-30, and 56 are pending.

APPLICANT'S INVENTION

2. Applicant's invention is directed to microspheres and uses thereof as set forth in independent claims 1, 11, and 22.

RESPONSE TO APPLICANT'S ELECTIONS

3. Applicant's election of Group I, claims 1-21, directed to a microsphere comprising crosslinked polyvinyl alcohol filed 8/29/05 is acknowledged. The election is viewed as an election without traverse since Applicant did not point out the supposed errors of the restriction requirement. Hence, the restriction is deemed proper and is made FINAL.

WITHDRAWN CLAIMS

4. Claims 22-30 are withdrawn from further consideration by the examiner, 37 CFR 1.142(b), as being drawn to a non-elected invention.

112 REJECTIONS

5. The following is a quotation of the second paragraph of 35 U.S.C. 112:

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The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

6. Claims 6, 7, and 18 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claims 6, 7, and 18: The claims as written are ambiguous because it is unclear what the abbreviation 'CM' state for. In addition, it is unclear what species are encompassed by the terms 'a natural biological cell adhesion agent' and 'a synthetic biological cell adhesion agent'. Applicant is respectfully requested to point to page(s) and line(s) numbers wherein support for such terminology is disclosed.

103 REJECTIONS

7. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

8. Claims 1, 4-6, 11, 15-18, and 56 are rejected under 35 U.S.C. 103(a) as being unpatentable over **Bachtsi et al** (J. Microencapsulation, 1995, Vol. 12, No. 1, pp. 23-35).

Bachtsi et al disclose an experimental investigation of enzyme release from polyvinyl alcohol (PVA) crosslinked microspheres. The spherical crosslinked particles range in size from 30 to 80 microns. The crosslinked particles, after washing and

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drying, were placed into a protease enzyme solution for loading (see entire document, especially, abstract; page 25-26, 'Particle preparation'; page 27, first complete paragraph). The use of crosslinked PVA hydrogel matrices may be used as delivery systems. The release of drugs from the crosslinked swellable natural polymer matrices (i.e., albumin and gelatin) has been investigated by others in the art (page 24, first complete paragraph). In Table 1 on page 28, enzyme loading into a hydrogel PVA particle having various percentages of PVA crosslinking is disclosed. The percentages include 1, 3, 5, 10, and 20%. Bachtisi et al fail to specifically disclose that the microspheres that they generated are sterile. However, it would have been obvious to one of ordinary skill in the art at the time the invention was made to modify the invention of Bachtisi et al and generate sterile microspheres because the reference discloses that crosslinked PVA hydrogel matrices may be used as drug delivery systems (see page 33, 'Conclusions').

9. Claims 1, 8, 9, 11, 19, and 20 are rejected under 35 U.S.C. 103(a) as being unpatentable over Barnes et al (Cytometry, 1999, Vol. 36, No. 3, pp. 169-175).

Barnes et al disclose fluorescence imaging in polymer microspheres. The microspheres are spherical (see entire document, especially, abstract; page 172, right column, last paragraph). In addition, Barnes et al disclose that polyvinyl alcohols (PVAs) are widely used in drug delivery and biological systems. While PVA is slightly more difficult to work with, it is much more amenable to fluorescence imaging studies because the photostability of rhodamine dyes is considerably higher than in

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polyethylene glycols. The particle diameter was 8.712 +/- 0.002 micron. Also, Barnes et al disclose that for microscopy studies, a fall distance of about 20 centimeters was used to ensure that the particles were dry when collected on the slide (page 170, 'Experiment Design and Results'). Thus, it would have been obvious to one of ordinary skill in the art at the time the invention was made to modify the invention of Barnes et al and generate sterile microspheres because the reference disclose PVA containing microspheres for imaging purposes. In addition, the reference discloses that the microspheres are useful for delivery systems.

CLAIM OBJECTIONS

10. Claims 7, 10, and 21 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.


The limitations of claims 7, 10, and 21 in combination with their respective intervening claims are distinguished over the prior art of record because the prior art neither anticipates nor renders obvious the addition limitations present in the claims.

11. Any inquiry concerning this communication or earlier communications from the examiner should be directed to D. L. Jones whose telephone number is (571) 272-0617. The examiner can normally be reached on Mon.-Fri., 6:45 a.m. - 3:15 p.m..

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael Hartley can be reached on (571) 272-0616. The fax phone number for the organization where this application or proceeding is assigned is (571) 273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).



D. L. Jones
Primary Examiner
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November 14, 2005